

Applicants : Ron S. Israeli, et al  
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*--96.*

nucleic acid molecule encoding a prostate specific membrane antigen; e) amplifying any cDNA to which the primer hybridizes to, so as to obtain an amplification product; f) detecting the amplification product, thereby detecting the presence of the nucleic acid molecule encoding the prostate specific membrane antigen in the sample.--

(New) The method of claim 93, wherein the sample is blood, lymph nodes, bone marrow, semen, or urine.--

#### REMARKS

Claims 1-77 and 79-92 were pending in the subject application. Applicants have hereinabove canceled claims 1-77 and 79-92, and added new claims 93-96. Accordingly, claims 93-96 are under examination in the subject application.

Support for claims 90-96 may be found inter alia in the specification and specifically as follows: page 24, lines 20 - page 26. Line 26; and page 39, lines 26-36. Applicants maintain that the amendments to the claims do not constitute new matter. Accordingly, applicants respectfully request entry of claims 93-96.

In the February 19, 1997 Office Action, the Examiner asserted that Restriction under 35 U.S.C. 121 to one of the following inventions is required: I. Claims 1-11, 14-21, 74-76 drawn to a nucleic acid encoding a prostate specific antigen; II. Claims 12 and 13, drawn to a method of detecting said antigen with said nucleic acid; III. Claims 23,27,28,29,31 drawn to a ligand; IV. Claim 22, drawn to a method of using the ligand to determine if said ligand binds to the antigen; V. Claims 24 and 25, drawn to the prostate specific antigen; VI. Claims 26, drawn to a method of making a ligand; VII. Claim 30, drawn to a method of using the

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ligand for imaging the prostate cancer; VIII. Claims 32-36, drawn to an antibody; IX. Claims 37 and 38, drawn to a therapeutic agent comprising said antibody and cytotoxic agent; X. Claims 39-45, drawn to a method of detection using said antibody and composition comprising said antibody and carrier (or radioisotope); XI. Claim 46, drawn to a method of purifying said antigen; XII. Claims 47 and 48 drawn to a transgenic mammal; XIII. Claims 49-72, 84-89 drawn to a method of treatment using the nucleic acid of said antigen; and XIV. Claims 78-83, 90-92 drawn to a method of detection using primers of said antigen.

The Examiner asserted that the inventions are distinct, each from the other because of the following reasons: Groups I, II, XII, XIII and XIV drawn to a nucleic acid and Groups III, IV, V, VI, VII, VIII, IX, X, and XI, drawn to antigens, antibodies, and ligands are distinct inventions since they are drawn to product with different structure and biological properties.

The Examiner asserted that Group I and II are related as product and process of use. The Examiner asserted that the inventions can be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)), in the instant case the DNA can be used for treatment.

The Examiner asserted that Group I and XIII are related as product and process use. The Examiner asserted that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product claimed can be practiced with another materially different product or (2) the product can be used in a materially different process of using that product (MPEP § 806.05 (h)), in the instant case the DNA can be used for the detection by mRNA hybridizing

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to the nucleic acid molecule.

The Examiner asserted that Group I and XIV are related as product and process use. The Examiner asserted that the inventions can be shown to be distinct if either both of the following can be shown: (1) the process for using the product claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)), in the instant case the DNA can be used for treatment.

The Examiner asserted that Group I,II,XIII,XIV, are drawn to a nucleic acid and Group XII drawn to transgenic animal are distinct inventions since they are drawn to a product with different structure and biological properties. Furthermore, the method of making DNA from Group I, II,XIII and XIV does not require the transgenic animal of Group XII. The Examiner asserted that Group II, drawn to a method of detecting said antigen is distinct from Group XIII, and XIV since the method of each group require different reagents and parameters.

The Examiner asserted that Group III and Group IV are related as product and process of use. The Examiner asserted that the inventions can be shown to be different if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in materially different process of using that product (MPEP § 806.05 (h)), in the instant case the ligand can be used for imaging prostate cancer.

The Examiner asserted that Group III and Group VII are related as product and process of use. The Examiner asserted that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as

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claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)), in the instant case the ligand can be used to determine if the ligand binds to the antigen.

The Examiner asserted that Group VI and III are related as process of making a product made. The Examiner asserted that the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)), in the instant case the process as claimed to make antibodies.

The Examiner asserted that Group III, IV, VI, VII drawn to a ligand is distinct from Group V, VIII, IX, X, XI, XII and XIV drawn to antigens, antibodies, and transgenic animals since they are drawn to product with different structure and biological properties.

The Examiner asserted that Group IV, VI and VII are distinct from each other since the methods require different parameters and reagents. The Examiner asserted that the inventions are distinct, each from the other because Group V and XI drawn to antigen is distinct from Group VII, IX, X, XII, XIII, and XIV drawn to antibodies, and transgenic animals since they are drawn to products with different structure and biological properties. The Examiner asserted that the inventions are distinct, each from the other because Group XI and V are related as process and product made. The Examiner asserted that the inventions are distinct if either or both of the following can be shown: (1) that the product as claimed can be used to make other and materially different process or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)),

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in the instant case the protein can be made by recombinant means or Merrifield chemical synthesis.

The Examiner asserted that Group VIII and Group IX are related as product and process of use. The Examiner asserted that the inventions are distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)), in the instant case the antibody can be used for detection.

The Examiner asserted that Group VIII and Group X are related as product and process of use. The Examiner asserted that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)), in the instant case the antibody can be used for treatment.

The Examiner asserted that Group IX and X are distinct from each other since the methods require different parameters and reagents. The Examiner asserted that the inventions are distinct, each from the other because Groups XIII and XIV are distinct from each other since the methods require different parameters and reagents.

The Examiner asserted that because these inventions are distinct for the reasons given above and have acquired a different status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In response, without conceding the correctness of the Examiner's assertion, applicants have canceled claims 1-92 and filed new

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claims 93-96. The subject matter as defined by claims 93-96 is directed to a method of detecting micrometastatic prostate tumor cells of a subject.

Applicants note that claims 93-96 are contained in Group II, claims 12 and 13 and thus by canceling the claims, and adding new claims 93-96, applicants are in effect electing Group II.

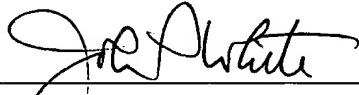
Applicants point out that the subject matter defined by claims 93 - 96 are connected and are not independent inventions. Further, applicants maintain that it would not be a serious burden on the Examiner to conduct a search for any prior art for the now claimed polypeptide.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

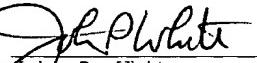
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No fee, except the fee of \$465.000 for a three-month extension of time is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White  
Registration No. 28,678  
Attorney for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.
 <span style="margin-left: 100px;">6/9/97</span>
John P. White Registration No. 28,678